



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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November 19, 1998

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-4-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Demetri Fortis, President
African Home Supply
207-209 South Water Market
Chicago, Illinois 60608

Dear Mr. Fortis:

An inspection of your firm by the U.S. Food and Drug Administration (FDA) on August 19-24, 1998, documented numerous insanitary conditions at your food storage warehouse, which caused the stored food products to become adulterated.

Our inspection showed that food products stored and held at your facility were found adulterated. These adulterated food products are in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). These adulterated food products: a) consisted in whole or in part of filthy substances, such as rodent fecal pellets, live insects, water from leaking sewage line and from rain leakage; and b) had been held under insanitary conditions whereby they have become contaminated with rodent, insect, bird, and sewage filth.

Evidence of rodent activity in the form of a live mouse in the basement, excreta pellets and gnawed paper material were observed on the third floor. Rodent excreta pellets were observed on bags of wheat flour along with flour spillage in this area during the inspection.

Our investigators observed live insects on bags of flour on the third floor; three of the bags were open with live insects near the openings. Bird fecal droppings and feathers were observed on the third floor near food storage and near an opening to the exterior of the elevator shaft.

Water soaked bags of flour were observed under a leaking sewer line in the basement. Sewage water from a damaged sewer line was observed pooling on the first floor. Water damaged flour was observed under an unprotected ceiling exhaust vent on the third floor.

Doors leading to the exterior of the building were not tight fitting. There was an opening six inches wide by one-half inch high under a door on the first floor. A second floor door leading to a fire escape had a one inch by one inch opening under it. Miscellaneous materials such as construction equipment, pallets, etc., blocked avenues of inspection along walls.

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Our laboratory confirmed the findings of rodent excreta, dermestid larva, and merchant grain beetle sampled from the warehouse during the inspection.

In addition, your firm was receiving and distributing a product called "Woodward's Gripe Water ***FOR THE DISORDERS OF CHILDREN***" without an approved New Drug Application (NDA). This product is a new drug within the meaning of Section 201(p) and is an unapproved New Drug within the meaning of Section 505(a) of the Act.

The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Federal regulations. The investigators reported you have destroyed lots of flour and other products that showed evidence of contamination and began to take some steps to correct the insanitary conditions in your facility. We request that you take prompt action to correct all violations.

Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take and have taken to correct and prevent the recurrence of these objectionable conditions. Provide the time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/

Raymond V. Mlecko
District Director